

IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF ARKANSAS
FAYETTEVILLE DIVISION

US DISTRICT COURT
WESTERN DIST ARKANSAS
FILED

JUN 29 2017

DOUGLAS F. YOUNG, Clerk
By
Deputy Clerk

MICHAEL RAY LEWIS, individually
and on behalf of all others similarly situated,

Plaintiff,

-against-

PURDUE PHARMA L.P.; PURDUE
PHARMA, INC.; THE PURDUE
FREDERICK COMPANY, INC.;
TEVA PHARMACEUTICALS USA, INC.;
CEPHALON, INC.; JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC. n/k/a JANSSEN
PHARMACEUTICALS, INC.; JANSSEN
PHARMACEUTICA INC. n/k/a JANSSEN
PHARMACEUTICALS, INC.; ENDO
HEALTH SOLUTIONS INC.; ENDO
PHARMACEUTICALS, INC.;
WATSON PHARMACEUTICALS, INC.
n/k/a ACTAVIS, INC.; WATSON
LABORATORIES, INC.; ACTAVIS LLC;
And ACTAVIS PHARMA, INC. f/k/a
WATSON PHARMA, INC.,

Defendants.

CLASS ACTION COMPLAINT

Case No. **17-5118 PKH**

JURY TRIAL DEMANDED

Plaintiff Michael Ray Lewis brings this lawsuit against Defendants Purdue Pharma L.P., Purdue Pharma, Inc., The Purdue Frederic Company, Inc., Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc. Endo Health Solutions Inc., Endo Pharmaceuticals, Inc., Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc., Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. (collectively, the "Defendants"). In order to remedy the harm to Plaintiff and the Class arising from Defendants' wrongful conduct and the unjust profits

and other benefits reaped by the Drug Companies, Plaintiff brings this action on behalf of himself and a class of Arkansans, as defined below.

I. INTRODUCTION

1. Drug companies should never place their desire for profits above the health and well-being of their customers or the communities where those customers live. Because they know prescribing doctors and other health-care providers rely on drug companies' statements in making treatment decisions, drug companies must tell the truth when marketing their drugs and ensure that their marketing claims are supported by science and medical evidence.

2. Defendants broke these simple rules and helped unleash a healthcare crisis that has had far-reaching financial, social, and deadly consequences in the State of Arkansas.

3. Defendants manufacture, market, and sell prescription opioids ("Opioids"), including brand-name drugs like Oxycontin and Percocet, and generics like oxycodone and hydrocodone, which are powerful narcotic painkillers. Historically, because they were considered too addictive and debilitating for the treatment of chronic pain (like back pain, migraines, and arthritis),¹ Opioids were used only to treat short-term acute pain or for palliative (end-of-life) care.

4. By the late 1990s, however, and continuing today, each Defendant began a marketing scheme designed to persuade doctors and patients that Opioids can and should be used for chronic pain, a far broader group of patients much more likely to become addicted and suffer other adverse effects from the long-term use of Opioids. In connection with this scheme, each Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of Opioids while overstating the benefits of using them for chronic pain. As to the risks, Defendants falsely and misleadingly, and contrary to the

¹ In this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

language on their drugs' labels: (1) downplayed the serious risk of addiction; (2) promoted the concept of "pseudoaddiction" and thus advocated that the signs of addiction should be treated with more Opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that Opioid dependence and withdrawal are easily managed; (5) denied the risks of higher Opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" Opioid formulations to prevent abuse and addiction. Conversely, Defendants also falsely touted the benefits of long-term Opioid use, including the supposed ability of Opioids to improve function and quality of life, even though there was no "good evidence" to support Defendants' claims.

5. Defendants disseminated these common messages to reverse the popular and medical understanding of Opioids. They disseminated these messages directly, through their sales representatives, and in speaker groups led by physicians Defendants recruited for their support of Defendants' marketing messages. Borrowing a page from Big Tobacco's playbook, Defendants also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" ("KOLs") and (b) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (appropriately described as "Front Groups"). Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients have traditionally relied on for ostensibly "neutral" guidance, such as treatment guidelines, Continuing Medical Education ("CME") programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, Defendants persuaded doctors and patients that what they had long known – that Opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and quite the opposite, that the compassionate treatment of pain *required* Opioids.

6. Each Defendant knew that its misrepresentation of the risks and benefits of Opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of each Defendant's misrepresentations has been confirmed by the U.S. Food and Drug Administration (the "FDA") and the Centers for Disease Control and Prevention (the "CDC"), including by the CDC in its *Guideline for Prescribing Opioids for Chronic Pain* (submitted as Exhibit 1 to this Complaint), issued in 2016 and approved by the FDA (the "2016 CDC Guideline"). Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have also entered into settlement agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint in other jurisdictions. Yet even now, each Defendant continues to misrepresent the risks and benefits of long-term Opioid use in Arkansas and continues to fail to correct its past misrepresentations.

7. Defendants' efforts were wildly successful. Opioids are now the *most* prescribed class of drug; they generated \$11 billion in revenue for drug companies in 2014 alone. In an open letter to the nation's physicians in August 2016, the United States Surgeon General at the time expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain." Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at <http://turnthetidex.org/> (submitted as Exhibit 2 to this Complaint). This epidemic, fueled by Opioids lawfully prescribed by doctors, has resulted in a flood of prescription Opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or legitimately obtain Opioids, they often turn to the street to buy prescription Opioids or even heroin.

8. It is hardly necessary to say – in this County or this State – that Arkansas is now awash in Opioids and engulfed in a public health crisis the likes of which have not been seen before. Since 2012, Arkansas has ranked in the top 10 among all states for the number of prescribed Opioids. Ark. Center Health Improvement, *Prevention of Opioid Pain Reliever Misuse in Arkansas: Fact Sheet*, Sept. 2015 (submitted as Exhibit 3 to this Complaint). By 2016, the total number of Opioid doses prescribed to Arkansas patients had soared to 109 million – enough to supply every man, woman, and child in the state with **38 pills each**. Dwain Hebda, *The Lost Generation (Arkansas and its Children are Caught in a Nationwide Opioid Epidemic)*, Savvy Mag., June 2017, at 27 (submitted as Exhibit 4 to this Complaint). Focusing only on legally obtained drugs prescribed by doctors, and disregarding illegal consumption for which no records exist, a staggering 1.7 million Opioid prescriptions were written last year in Arkansas. *See id.* This in a state with a *total* population of 2.978 million people, according to the United States Census Bureau. *Demographics of Arkansas*, Wikipedia, https://en.wikipedia.org/wiki/Demographics_of_Arkansas (last visited June 6, 2017).

9. The results of Arkansas's Opioid crisis has been catastrophic. Opioids have become the main source of unintentional drug overdose in the state and, due to the vast supply of Opioids, the number of annual deaths attributable to unintentional drug overdoses has rapidly increased in recent years. The CDC reports that the number of Arkansas deaths from drug overdose between 2013 and 2014 – a total of 675 fatalities – increased by 13.5 percent. Brian D. Sanderford, *Narcan's Importance Grows as Prescription Drug Abuse Increases*, Southwest Times Record, May 22, 2016, <http://www.swtimes.com/news/narcans-importance-grows-prescription-drug-abuse-increases> (submitted as Exhibit 5 to this Complaint). Opioid deaths are up 200 percent overall since 2000. Hebda, *supra* ¶ 8, at 27.

10. But even these alarming statistics do not fully illustrate the toll of prescription Opioid abuse on patients and their families, as the dramatic increase in Opioid prescriptions to treat chronic pain has resulted in a population of addicts who seek drugs from doctors. Efforts by physicians to reverse course for a chronic pain patient with long term dependence on Opioids are often thwarted by a secondary criminal market well-stocked by a pipeline of drugs that are diverted to supply these patients.

11. Prescription Opioid abuse has not displaced heroin, but rather triggered a resurgence in its use, imposing additional burdens on state agencies and others that address heroin use and addiction. Individuals who are addicted to prescription Opioids often transition to heroin because it is a less expensive, readily available alternative that provides a similar high. *See, e.g.,* Kate Jordan, *Police: Heroin becoming more Prevalent in Fort Smith Region*, Southwest Times Record, Oct. 2, 2016, www.swtimes.com/news/20161002/police-heroin-becoming-more-prevalent-in-fort-smith-region (submitted as Exhibit 6 to this Complaint) (“One of the reasons heroin is making a come back is because people are so addicted to pharmaceuticals – opiates and opioids, and heroin is cheaper.” (quotation omitted)).

12. Many thousands of Arkansans suffer from chronic pain, which takes an enormous toll on their health, lives, and families. These patients deserve both appropriate care and the ability to make decisions based on accurate, complete information about risks and benefits. But Defendants’ deceptive marketing campaign deprived Arkansas patients and their doctors of the ability to make informed medical decisions and, instead, caused important, sometimes life-or-death decisions to be made based not on science, but on hype. Defendants deprived patients, their doctors, and health care payors of the chance to exercise informed judgment and subjected them to enormous costs and suffering.

13. Defendants' misrepresentations and deceptive conduct has exacted, and foreseeably so, a heavy financial burden on Arkansans. To redress and punish these violations of the state's statutory and common law, including the Arkansas Deceptive Trade Practices Act, Ark. Code Ann. §§ 4-88-101 to -115 (the "ADTPA"), Plaintiff, on his own behalf and on behalf of a Class of Arkansans as defined in this Complaint, seeks damages for the actual damage and injury he and the Class have suffered by paying for excessive Opioid prescriptions and in connection with the results of those prescriptions (for example, and not limited to, addiction treatment costs). Plaintiff and the Class also seek attorneys' fees and costs pursuant to Ark. Code Ann. § 4-88-113(f). Plaintiff also seeks costs of future medical monitoring made necessary by Defendants' unlawful actions.

II. JURISDICTION AND VENUE

14. This Court has jurisdiction over this civil action pursuant to 28 U.S.C. § 1332(d) because it is brought as a class action, on behalf of a Class of over 100 Class Members, whose claims aggregate in excess of \$5 million, and which includes members whose state citizenship is diverse from that of one or more Defendants.

15. This Court has personal jurisdiction over each Defendant. At all times material to this action, each Defendant was conducting business in the State of Arkansas. Plaintiff and Class Members purchased in the State of Arkansas pharmaceutical products sold and manufactured by the Defendants, and a substantial part of the transactions which give rise to this action took place in this District.

16. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) on the grounds that a substantial part of the events and omissions giving rise to the claims at issue occurred in this judicial district.

17. The named Plaintiff and the Class Members assert no federal question. The state law causes of action asserted in this Complaint are not federally preempted.

III. PARTIES

18. Plaintiff, MICHAEL RAY LEWIS, is a resident of Sebastian County, Arkansas, who was first prescribed Opioids in or around 2005 and who, over the following years, received numerous prescriptions for various Opioids (including Oxycodone, Percocet, and Hydrocodone). Plaintiff was subsequently treated for addiction related to his Opioid prescriptions.

19. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and the PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue").

20. Purdue manufactures, promotes, sells, and distributes Opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States and Arkansas. OxyContin is Purdue's best selling Opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up almost four-fold from its 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (popularly known as painkillers).

21. CEPHALON, INC. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011.

22. Cephalon manufactures, promotes, sells, and distributes Opioids such as Actiq and Fentora in the United States and Arkansas. Actiq and Fentora have been approved by the FDA only for the “management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.”² In 2008, Cephalon pleaded guilty to a criminal violation of the Federal Food, Drug, and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay \$425 million.

23. Teva Ltd., Teva USA, and Cephalon work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its “specialty medicines” division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon Opioids marketed and sold in Arkansas, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. The United States is the largest of Teva Ltd.’s global markets, representing 53% of its global revenue in 2015. (Throughout the remainder of this Complaint, references to “Cephalon” encompass Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc.).

24. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of

² “Breakthrough pain” is a short-term flare of moderate-to-severe pain in patients with otherwise stable persistent pain.

JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as JANNSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to as "Janssen.").

25. Janssen manufactures, promotes, sells, and distributes drugs in the United States and Arkansas, including the Opioid drug Duragesic. Before 2009, Duragesic accounted for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed and sold the Opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

26. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as "Endo.")

27. Endo develops, markets, and sells prescription drugs, including the Opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the United States and Arkansas. Opioids

made up roughly \$403 million of Endo's overall revenues of \$3 billion in 2012. Opana ER yielded \$1.15 billion in revenue from 2010 to 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic Opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States and Arkansas, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

28. WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the combined company adopted the name of Actavis, Inc. as of January 2013 before finally settling on Actavis PLC in October 2013. WATSON LABORATORIES, INC. is a Nevada Corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. (Allergan PLC, Actavis PLC, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as "Actavis.")

29. Actavis manufactures, promotes, sells, and distributed Opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the United States and Arkansas. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

IV. FACTUAL ALLEGATIONS

30. Before the 1990s, generally accepted standards of medical practice dictated that Opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or

for cancer or palliative (end-of-life) care. Due to the lack of evidence that Opioids improved patients' ability to function by overcoming pain, coupled with evidence of greater pain complaints as patients developed tolerance to Opioids over time and the serious risk of addiction and other side effects, the use of Opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe Opioids for chronic pain.

31. To take advantage of the lucrative market for chronic pain patients, each Defendant developed a well-funded marketing scheme based on deception. Each Defendant used both direct marketing and unbranded advertising disseminated by seemingly independent third parties to spread false and deceptive statements about the risks and benefits of long-term Opioid use – statements that benefited not only themselves and the third-parties who gained legitimacy when Defendants repeated those statements, but also other Defendants and Opioid manufacturers. Yet these statements were not only unsupported by or contrary to the scientific evidence, they were also contrary to pronouncements by and guidance from the FDA and CDC based on that evidence. They also targeted susceptible prescribers and vulnerable patient populations.

A. Defendants Used Multiple Avenues To Disseminate Their False And Deceptive Statements About Opioids

32. Defendants spread their false and deceptive statements by marketing their branded Opioids directly to doctors and patients in Arkansas. Defendants deployed throughout the state of Arkansas seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of Opioids for the treatment of chronic pain.

1. Defendants spread and continue to spread their false and deceptive statements through direct marketing of their branded Opioids

33. Defendants' direct marketing of Opioids generally proceeded on two tracks. First, each Defendant conducted and continues to conduct advertising campaigns touting the purported benefit of their branded drugs. For example, Defendants spent more than \$14 million on medical journal advertising of Opioids in 2011, nearly triple what they spent in 2001. The amount included \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo.

34. A number of Defendants' branded ads deceptively portrayed the benefits of Opioids for chronic pain. For example, Endo distributed and made available on its website opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. Endo and Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, but they may continue to disseminate them in Arkansas.

35. Second, each Defendant promoted the use of Opioids for chronic pain through "detailers" – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs. Defendants have not corrected this misinformation. Instead, each Defendants devoted and continues to devote massive resources to direct sales contacts with doctors. In 2014 alone, Defendants spent \$168 million on detailing branded Opioids to doctors. This amount is twice as much as Defendants spent on detailing in 2000. The amount includes

\$108 million spent by Purdue, \$34 million by Janssen, \$13 million by Cephalon, \$10 million by Endo, and \$2 million by Actavis.

36. Defendants' detailers have been reprimanded for their deceptive promotions. A July 2010 "Dear Doctor" letter mandated by the FDA required Actavis to acknowledge to the doctors to whom it marketed its drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of Opioids" and, specifically, the risk that "Opioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

37. Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular Opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of Opioids.

38. Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Even without such studies, Defendants purchase, manipulate, and analyze some of the most sophisticated data available in *any* industry, data available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by individual doctor, which in turn

allows them to target, tailor, and monitor the impact of their core messages. Thus, Defendants *know* their detailing to doctors is effective.

39. Defendants employed the same marketing plans and strategies and deployed the same message in Arkansas as they did nationwide. Across the pharmaceutical industry, “core message” development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Defendants’ messages are accurately and consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

40. Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. Defendants’ sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to check on both their performance and compliance.

2. Defendants used a diverse group of seemingly independent third parties to spread false and deceptive statements about the risks and benefits of Opioids

41. Defendants also deceptively marketed Opioids through unbranded advertising – *i.e.*, advertising that promotes Opioid use generally but does not name a specific Opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote Opioids for the treatment of chronic pain. Much as Defendants

controlled the distribution of their “core messages” via their own detailers and speaker programs, Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, CMEs, and medical conferences and seminars. To this end, Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

42. Defendants also marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long-term Opioid use for chronic pain.

43. Defendants’ deceptive unbranded marketing often contradicted what they said in their branded materials reviewed by the FDA. For example, Endo’s unbranded advertising contradicted its concurrent, branded advertising for Opana ER:

Pain: Opioid Therapy (Unbranded)	Opana ER Advertisement (Branded)
“People who take opioids as prescribed usually do not become addicted. ”	“All patients treated with opioids require careful monitoring for signs of abuse and addiction, since use of opioid analgesic products carries the risk of addiction even under appropriate medical use. ”

a. Key Opinion Leaders (“KOLs”)

44. Defendants also spoke through a small circle of doctors who, upon information and belief, were selected, funded, and elevated by Defendants because their public positions supported the use of Opioids to treat chronic pain. These doctors became known as “key opinion leaders” or “KOLs.”

45. Defendants paid KOLs to serve as consultants on their advisory boards and to give talks or present CMEs, and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of Opioids to treat chronic pain, repaying Defendants by advancing their marketing goals. KOLs’ professional reputations became dependent on continuing to promote a pro-Opioid message, even in activities that were not directly funded by Defendants.

46. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic Opioid therapy. Defendants have created opportunities for KOLs to participate in research studies Defendants suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic Opioid therapy.

47. Defendants’ KOLs also served on committees that developed treatment guidelines that strongly encourage the use of Opioids to treat chronic pain, and on the boards of pro-Opioid advocacy groups and professional societies that develop, select, and present CMEs. Defendants were able to direct and exert control over each of these activities through their KOLs. The 2016 CDC Guideline recognizes that treatment guidelines can “change prescribing practices.”

48. Pro-Opioid doctors are one of the most important avenues that Defendants use to spread their false and deceptive statements about the risks and benefits of long-term Opioid use. Defendants knew that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic Opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website *In the Face of Pain* failed to disclose that doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials. *See In re Purdue Pharma L.P., Assurance of Discontinuance* ¶ 18, at 8 (N.Y. Att. Gen. Aug. 19, 2015) (submitted as Exhibit 7 to this Complaint) (“[T]he website failed to disclose that from 2008 to 2013, Purdue made payments totaling almost \$231,000, for speaker programs, advisory meetings, and travel costs, to 11 of the Advocates whose testimonials appeared on the site.”).

49. Thus, even though some of the KOLs have recently moderated or conceded the lack of evidence for many of the claims they made, these admissions did not reverse the effect of the false and deceptive statements that continue to appear nationwide and throughout the State of Arkansas in Defendants' own marketing as well as treatment guidelines, CMEs and other seminars, scientific articles and research, and other publications available in paper or online.

50. Defendants utilized many KOLs, including many of the same ones. Two of the most prominent are described below.

(1) Russell Portenoy

51. Dr. Russell Portenoy, former chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received

research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

52. Dr. Portenoy was instrumental in opening the door for regular use of Opioids to treat chronic pain. He served on the American Pain Society (“APS”)/American Academy of Pain Medicine (“AAPM”) Guideline Committees, which endorsed the use of Opioids to treat chronic pain, first in 1997 and again in 2009. He was also a member of the board of the American Pain Foundation (“APF”), an advocacy organization almost entirely funded by Defendants.

53. Dr. Portenoy also made frequent media appearances promoting Opioids and spreading misrepresentations. He appeared on *Good Morning America* in 2010 to discuss the use of Opioids long-term to treat chronic pain. On this widely-watched program, broadcast in Arkansas and across the country, Dr. Portenoy claimed: “Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted.” *Good Morning America Television Broadcast*, ABC News (Aug. 30, 2010).

54. To his credit, Dr. Portenoy later admitted that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that weren’t true.” These lectures falsely claimed that fewer than 1% of patients would become addicted to Opioids. According to Dr. Portenoy, because the primary goal was to “destigmatize” Opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that “[d]ata about the effectiveness of Opioids does not exist.” Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012 (submitted as Exhibit 8 to this Complaint).

Portenoy candidly stated: “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did.” *Id.*

(3) Lynn Webster

55. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was president in 2013 and is a current board member of AAPM, a front group that ardently supports chronic Opioid therapy. He is Senior Editor of *Pain Medicine*, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly \$2 million from Cephalon).

56. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice’s Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster’s former patients at the Lifetree Clinic have died of Opioid overdoses.

57. Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse Opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe Opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster’s Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue.

58. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patients’ Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended

use of risk screening tools, urine testing, and patient agreements as a way to prevent “overuse of prescriptions” and “overdose deaths.” This webinar was available to and was intended to reach Arkansas doctors.

59. Dr. Webster also was a leading proponent of the concept of “pseudoaddiction,” the notion that addictive behaviors should not be seen as warnings, but as indications of undertreated pain. In Dr. Webster’s description, the only way to differentiate the two was to *increase* a patient’s dose of Opioids. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), a book that is still available online, when faced with signs of aberrant behavior, increasing the dose “in most cases . . . should be the clinician’s first response.” Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that “[pseudoaddiction] obviously became too much of an excuse to give patients more medication.” John Fauber, *Networking Fuels Painkiller Boom*, Bangor Daily News (Feb. 19, 2012) (submitted as Exhibit 9 to this Complaint).

b. Front Groups

60. Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote Opioids for the treatment of chronic pain. Under the direction and control of Defendants, these “Front Groups” generated treatment guidelines, unbranded materials, and programs that favored chronic Opioid therapy. They also assisted Defendants by responding to negative articles, by advocating against regulatory changes that would limit Opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Defendants.

61. These Front Groups depended on Defendants for funding and, in some cases, for survival. Defendants also exercised control over programs and materials created by these groups

by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, Defendants made sure that the Groups would generate only the messages Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

62. Defendants Cephalon, Endo, Janssen, and Purdue utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society (“APS”), American Geriatrics Society (“AGS”), the Federation of State Medical Boards (“FSMB”), American Chronic Pain Association (“ACPA”), American Society of Pain Education (“ASPE”), National Pain Foundation (“NPF”), and Pain & Policy Studies Group (“PPSG”).

(1) American Pain Foundation (“APF”)

63. The most prominent of Defendants’ Front Groups was APF, which received more than \$10 million in funding from Opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half that funding; Purdue was next, at \$1.7 million.

64. APF issued education guides for patients, reporters, and policymakers that touted the benefits of Opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote Opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning soldiers. APF also engaged in a significant multimedia campaign – through radio, television, and the internet – to educate patients about their “right” to pain treatment, namely Opioids. All of the programs and materials were available nationally and were intended to reach Arkansans.

65. In addition to Perry Fine (a KOL from the University of Utah who received funding from Janssen, Cephalon, Endo, and Purdue), Russell Portenoy, and Scott Fishman (a KOL from the University of California, Davis who authored *Responsible Opioid Prescribing*, a publication sponsored by Cephalon and Purdue), all of whom served on APF's board and reviewed its publications, another board member, Lisa Weiss, was an employee of a public relations firm that worked for both Purdue and APF.

66. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about \$2.3 million from industry sources out of total income of about \$2.85 million in 2009; its budget for 2010 projected receipts of roughly \$2.9 million from drug companies, out of total income of about \$3.5 million. By 2011, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. As one of its board members, Russell Portenoy, explained, the lack of funding diversity was one of the biggest problems at APF.

67. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit Opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide "patient representatives" for Defendants' promotional activities, including for Purdue's *Partners Against Pain* and Janssen's *Let's Talk Pain*. APF functioned largely as an advocate for the interests of Defendants, not patients. Indeed, as early as 2011, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

68. In practice, APF operated in close collaboration with Opioid makers. On several occasions, representatives of the drug companies, often at informal meetings at Front Group conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund those activities and publications, knowing that drug companies would support projects conceived as a result of those communications.

69. APF assisted in other marketing projects for drug companies. One project funded by another drug company – *APF Reporter's Guide: Covering Pain and Its Management* (2009) – recycled text that was originally created as part of the company's training document.

70. The same drug company made general grants, but even then it directed how APF used them. In response to an APF request for funding to address a potentially damaging state Medicaid decision related to pain medication generally, the company representative responded, "I provided an advocacy grant to APF this year – this would be a very good issue on which to use some of that. How does that work?"

71. The close relationship between APF and the drug company highlighted in the previous paragraph was not unique, but mirrors relationships between APF and Defendants. APF's clear lack of independence – in its finances, management, and mission – and its willingness to allow Defendants to control its activities and messages support an inference that each Defendant that worked with it was able to exercise editorial control over its publications.

72. Indeed the U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of Opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and Defendants stopped funding it. Within days of being targeted

by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."

(2) American Academy of Pain Medicine ("AAPM")

73. The American Academy of Pain Medicine, with the assistance, prompting, involvement, and funding of Defendants, issued treatment guidelines and sponsored and hosted medical education programs essential to Defendants' deceptive marketing of chronic Opioid therapy.

74. AAPM received over \$2.2 million in funding since 2009 from Opioid manufacturers. AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM described the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, Cephalon, and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

75. AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on Opioids – 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization "at the forefront" of

teaching that “the risks of addiction are . . . small and can be managed.” Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), *available at* <http://www.medscape.org/viewarticle/500829> (submitted as Exhibit 10 to this Complaint).

76. AAPM’s staff understood they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-Opioid KOLs within the organization.

77. In addition, treatment guidelines have been particularly important in securing acceptance for chronic Opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are neither experts nor trained in the treatment of chronic pain. Treatment guidelines not only directly inform doctors’ prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

78. In 1997, AAPM and the American Pain Society jointly issues a consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed Opioids to treat chronic pain and claimed that the risk that patients would become addicted to Opioids was low. The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM’s website until 2011, and was taken down from AAPM’s website only after a doctor complained, though it lingers on the internet elsewhere.

79. AAPM and APS issued their own guidelines in 2009 (“AAPM/APS Guidelines”) and continued to recommend the use of Opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Caphalon, Endo, and Purdue.

80. The 2009 Guidelines promote Opioids as “safe and effective” for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache and Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on Opioids; the Guidelines have been cited 732 times in academic literature, were disseminated in Arkansas during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.

81. Defendants widely referenced and promoted the 2009 Guidelines without disclosing the acknowledged lack of evidence to support them.

82. Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term Opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum (“PCF”), which began in 2004 as an APF project. PCF is comprised of representatives from Opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from Defendants. Among other projects, PCF worked to ensure that an FDA-mandated

education project on Opioids was not unacceptably negative and did not require mandatory participation by prescribers, which Defendants determined would reduce prescribing.

B. Defendants' Marketing Scheme Misrepresented The Risks And Benefits Of Opioids

83. To convince doctors and patients in Arkansas that Opioids can and should be used to treat chronic pain, Defendants had to convince them that long-term Opioid use is both safe and helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks and benefits of long-term Opioid use, Defendants made claims that were not supported by or were contrary to scientific evidence. Even though pronouncements by and guidance from the FDA and the CDC based on that evidence confirm that their claims were false and deceptive, Defendants have not corrected them, or instructed their KOLs or Front Groups to correct them, and continue to spread them today.

1. Defendants falsely trivialized and/or failed to disclose the known risks of long-term Opioid use

84. To convince doctors and patients that Opioids are safe, Defendants deceptively trivialized and failed to disclose the risks of long-term Opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on Opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could be easily weaned from the drugs; (3) the use of higher Opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent Opioids both prevent abuse and overdose

and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, they continue to make them today.

85. Defendants falsely claimed that the risk of addiction is low and that addiction is unlikely to develop when Opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of Opioids. Some illustrative examples of these false and deceptive claims are described below:

- a. Actavis's predecessor caused a patient education brochure to be distributed in 2007 that claimed Opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative Opioid prescriptions from multiple sources, or theft. This publication is still available online.
- c. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the Opioid medications that are prescribed for them."
- d. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com.
- e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that Opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."
- f. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about Opioid addiction are "overestimated."

- g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed Opioids will become addicted and that pain is undertreated due to “misconceptions about opioid addiction[.]” This publication is still available online.
- g. Detailers for Purdue, Endo, Janssen, and Cephalon in Arkansas minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of Opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

86. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is “extensive evidence” of the “possible harms of Opioids (including opioid use disorder [an alternative term for Opioid addiction]).” The Guideline points out that “Opioid pain medication use presents serious risks, including . . . opioid use disorder” and that “continuing opioid therapy for 3 months substantially increases the risk for opioid use disorder.” *See Exhibit 1.*

87. The FDA further exposed the falsity of Defendants’ claims about the low risk of addiction when it announced changes to the labels for ER/LA Opioids in 2013 and for IR Opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘high potential for abuse’” and that Opioids “are associated with a substantial risk of misuse, abuse, NOWS [neonatal Opioid withdrawal syndrome], addiction, overdose, and death.” According to the FDA, because of the “known serious risks” associated with long-term Opioid use, including “risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death,” Opioids should be used only “in patients for whom alternative treatment options” like non-Opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction “can occur in patients appropriately prescribed [Opioids].”

88. The warnings on Defendants' own FDA-approved drug labels caution that Opioids "expose[] users to risks of addiction, abuse and misuse, which can lead to overdose and death," that the drugs contain "a substance with a high potential for abuse," and that addiction "can occur in patients appropriately prescribed" Opioids.

89. The State of New York, in a 2016 settlement agreement with Endo, found that Opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder." Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the State found that Endo had no evidence for that statement. *See Endo Health Solutions Inc.*, Assurance of Discontinuance ¶ 20, at 6 (N.Y. Att. Gen. Mar. 1, 2016) (submitted as Exhibit 11 to this Complaint). Consistent with this, Endo agreed not to "make statements that . . . opioids are generally non-addictive" or "that most patients who take opioids do not become addicted" in New York. Endo remains free, however, to make those statements in Arkansas.

90. Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more Opioids. Defendants have called this phenomenon "pseudoaddiction" – a term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Cephalon, Endo, Janssen, and Purdue – and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some illustrative examples of these deceptive claims are described below:

- a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain Opioids, and hoarding, are all signs of pseudoaddiction, rather than

true addiction. *Responsible Opioid Prescribing* remains for sale online. The 2012 edition, which also remains available online, continues to falsely teach that pseudoaddiction is real.

- b. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: “[P]seudoaddiction . . . refers to patient behaviors that may occur when pain is undertreated Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management.”
- c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient’s aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.
- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that “emerged in the literature” to describe the inaccurate interpretation of “[drug-seeking behaviors] in patients who have pain that has not been effectively treated.”
- e. Purdue sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or “overindulges in unapproved escalating doses.” The doctor treats this patient by prescribing a high-dose, long-acting Opioid.

91. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that Opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that “[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,” and that physicians should “reassess[] pain and function within 1 month” in order to decide whether to “minimize the risks of long-term opioid use by discontinuing opioids” because the patient is “not receiving a clear benefit.” See Exhibit 1.

92. Even one of the Defendants has effectively repudiated the concept of pseudoaddiction. In finding that “[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents,” the State of New York, in a 2016 settlement with Endo, reported that “Endo’s Vice President for Pharmacovigilance and Risk Management testified that he was not aware of any research validating the ‘pseudoaddiction’ concept” and acknowledged the difficulty in distinguishing “between addiction and ‘pseudoaddiction.’” Consistent with this, Endo agreed not to “use the term ‘pseudoaddiction’ in any training or marketing” in New York. Endo, however, remains free to do so in Arkansas.

93. Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe Opioids to patients predisposed to addiction. These misrepresentations were especially insidious because Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on Opioids. Defendants’ misrepresentations made these doctors feel more comfortable prescribing Opioids to their patients, and patients more comfortable starting on Opioid therapy for chronic pain. Some illustrative examples of these deceptive claims are described below:

- a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo’s speakers bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic Opioid therapy using a “maximally structured approach” involving toxicology screens and pill counts.
- b. Purdue sponsored a 2011 webinar, *Managing Patient’s Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent “overuse of prescriptions” and “overdose deaths.”

- c. As recently as 2015, Purdue has represented in scientific conferences that “bad apple” patients – and not Opioids – are the source of the addiction crisis and that once those “bad apples” are identified, doctors can safely prescribe Opioids without causing addiction.

94. Once again, the CDC Guideline confirms the falsity of these misrepresentations. The Guideline notes there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse – “for improving outcomes related to overdose, addiction, abuse, or misuse.” As a result, the Guideline recognizes that available risk screening tools “show insufficient accuracy for classification of patients as at low or high risk for [Opioid] abuse or misuse” and counsels that doctors “should not overestimate the ability of these tools to rule out risks from long-term opioid therapy.”

95. To underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on Opioids, Defendants falsely claimed that Opioid dependence can easily be addressed by tapering and that Opioid withdrawal is not a problem, and failed to disclose the increased difficulty of stopping Opioids after long-term use.

96. For example, A CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient’s Opioid dose by 10%-20% for 10 days. And Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation” without mentioning any hardships that might occur.

97. Defendants deceptively minimized the significant symptoms of Opioid withdrawal – which as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous

abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction – and grossly understated the difficulty of tapering, particularly after long-term Opioid use. Yet the 2016 CDC Guideline recognizes that the duration of Opioid use and the dosage of Opioids prescribed should be “limit[ed]” to “minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms,” because “physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days.” The Guideline further states that “tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence” and highlights the difficulties, including the need to carefully identify “a taper slow enough to minimize the symptoms and signs of opioid withdrawal” and to “pause[] and restart[]” tapers depending on the patient’s response. The CDC also acknowledges the lack of any “high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued.” *See Exhibit 1.*

98. Defendants falsely claimed that doctors and patients could increase Opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants’ efforts to market Opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients build up tolerance and lower dosages did not provide pain relief. Some illustrative examples are described below:

- a. Actavis’s predecessor created a patient brochure for Kadian in 2007 that stated, “Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction.” Upon information and belief, based on Actavis’s acquisition of its predecessor’s marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.

- b. Cephalon and Purdue sponsored APF's *Treatment Options a Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an Opioid, regardless of the dose currently prescribed. The guide stated that Opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available for sale online.
- c. Endo sponsored a website, painknowledge.com, which claimed in 2009 that Opioid dosages may be increased until "you are on the right dose of medication for your pain."
- d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was recently available on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."
- e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased Opioid dosages.
- f. Purdue's In the Face of Pain website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of Opioids, he or she should find another doctor who will.
- g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high Opioid dosages. This publication is still available online.
- h. Purdue sponsored a CME entitled *Overview of Management Options* that is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not Opioids, are unsafe at high dosages.
- i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, the "oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders," see www.cpdd.org, challenging the correlation between Opioid dosage and overdose.

99. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at

higher opioid dosage.” More specifically, the CDC explains that “there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages.” The CDC also states that “there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages.” That is why the CDC advises doctors to “avoid increasing dosages” above 90 morphine milligram equivalents per day. *See* Exhibit 1.

100. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events.” For example, the FDA noted that studies “appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality.”

101. Defendants’ deceptive marketing of the so-called abuse-deterrent properties of some of their Opioids has created false impressions that these Opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive. Catherine S. Hwang *et al.*, *Prescription Drug Abuse: A National Survey of Primary Care Physicians*, 175(2) JAMA Intern. Med. 302-04 (Dec. 8, 2014) (submitted as Exhibit 12 to this Complaint).

102. More specifically, Defendants have made misleading claims about the ability of their so-called abuse deterrent Opioid formulations to deter abuse. For example, Endo’s advertisement for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that there was no evidence Endo’s design “would provide a reduction in oral, intranasal, or intravenous abuse.” The FDA has subsequently taken the extraordinary action of “request[ing] that Endo Pharmaceuticals remove . . . Opana ER . . . from the market.” Maggie

Fox, *FDA Asks Drug Company to Pull its Opioid Opana Because of Abuse*, NBCNews.com (June 9, 2017), <http://www.nbcnews.com/storyline/americas-heroin-epidemic/fda-asks-drug-company-pull-its-opioid-opana-because-abuse-n770121> (submitted as Exhibit 13 to this Complaint). According to the FDA, Endo's reformulation of Opana ER "made things worse": "[P]ostmarketing data . . . demonstrate[s] a significant shift in the route of abuse of Opana ER from nasal to injection following the product's reformulation." *Id.* Moreover, Endo's own studies, which it fails to disclose, showed that Opana ER could still be ground and chewed.

103. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The State found these statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER. *See* Exhibit 11. Similarly, the 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies – even when they work – "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes." *See* Exhibit 1.

104. These numerous, longstanding misrepresentations of the risks of long-term opioid use spread by Defendants successfully convinced doctors and patients to discount those risks.

2. Defendants grossly overstated the benefits of chronic Opioid therapy

105. To convince doctors and patients that Opioids should be used to treat chronic pain, Defendants also had to persuade them that there was a significant upside to long-term Opioid use. But as the 2016 CDC Guidelines make clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with

outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)” and that other treatments were more or equally beneficial and less harmful than long-term opioid use. In 2013, the FDA stated that it was “not aware of adequate and well-controlled studies of opioids use longer than 12 weeks.” Despite this, Defendants falsely and misleadingly touted the benefits of long-term Opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have Defendants failed to correct these false and deceptive claims, they continue to make them today.

106. For example, Defendants falsely claimed that long-term Opioid use improved patients’ function and quality of life. Some illustrative examples are described below:

- a. Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve “stress on your body and your mental health,” and help patients enjoy their lives.
- b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.
- c. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as “a fact” that “opioids may make it easier for people to live normally.” The guide lists expected functional improvements from Opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.
- d. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled “Pain vignettes,” which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patient function.
- e. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Cephalon, Endo, and Purdue, taught that relief of pain by Opioids, by itself, improved patients’ function. The book remains for sale online.
- f. Cephalon and Purdue sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that Opioids

“give [pain patients] a quality of life we deserve.” The guide was available online until APF shut its doors in 2012.

- g. Endo’s NIPC website *painknowledge.com* claimed in 2009 that with Opioids, “your level of function should improve; you may find you are now able to participate in activities of daily living such as work and hobbies, that you were not able to enjoy when your pain was worse.” Elsewhere, the website touted improved quality of life (as well as “improved function”) as benefits of Opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC’s intent to make misleading claims about function, and Endo closely tracked visits to the site.
- h. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic Opioid therapy has been “shown to reduce pain and improve depressive symptoms and cognitive functioning.” The CME was disseminated via webcast.
- i. Janssen sponsored, funded, and edited a website, *Let’s Talk Pain*, in 2009, which featured an interview edited by Janssen claiming that Opioids allowed a patient to “continue to function.” This video is still available today on YouTube.
- j. Purdue sponsored the development and distribution of APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “multiple clinical studies” have shown that Opioids are effective in “improving daily function, psychological health, and health-related quality of life for chronic pain patients.” The Policymaker’s Guide was originally published in 2011 and is still available online today.
- k. Purdue’s, Cephalon’s, Endo’s, and Janssen’s sales representatives have conveyed and continue to convey the message that Opioids will improve patient function.

107. These claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline approved by the FDA concluded that “there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely.” See Exhibit 1 (emphasis added). The CDC reinforced this conclusion throughout its 2016 Guideline:

- “No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . .”

- “Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy.”
- “[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia.”

Id.

108. The CDC also noted that the risks of addiction and death “can cause distress and inability to fulfill major role obligations.” *See* Exhibit 1. As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

109. The 2016 Guideline was not the first time a federal agency repudiated Defendants’ claim that Opioids improved function and quality of life. In 2010, the FDA warned Actavis, in response to its advertising described in paragraph 37, that “[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient’s work, physical and mental functioning, daily activities, or enjoyment of life.” Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc’ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), *available at* <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm259240.htm>. And in 2008, the FDA sent a warning letter to an Opioid manufacturer, making it clear “that [the claims that] patients who are treated with the drug experience and improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience.”

110. Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to Opioids first for the treatment of chronic pain. Once again, these misrepresentations by Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA Opioids in 2013 and IR Opioids in 2016 to state that Opioids should only be used as a last resort “in patients for which alternative treatment options” like non-opioid drugs “are inadequate.” And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

111. In addition, Purdue misleadingly promoted OxyContin as being unique among Opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all times relevant to this action. According to Purdue’s own research, OxyContin wears off in under six hours in one-quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as “end of dose” failure, and the FDA found in 2008 that a “substantial number” of chronic pain patients taking OxyContin experience it. This not only renders Purdue’s promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

112. Purdue's competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Indeed, Purdue's sales representatives continue to tell Arkansas doctors that OxyContin lasts a full 12 hours.

113. Front Groups supported by Purdue likewise echoed these representations. For example, as an amicus brief submitted to the Supreme Court of Ohio by the American Pain Foundation, the National Foundation for the Treatment of Pain, and the Ohio Pain Initiative in support of Purdue, those amici represented:

Oxycontin is particularly useful for sustained long-term pain because it comes in higher, compact pills with a slow release coating. OxyContin pills can work for 12 hours. This makes it easier for patients to comply with dosing requirements without experiencing a roller-coaster of pain relief followed quickly by pain renewal that can occur with shorter acting medications. It also helps the patient sleep through the night, which is often impossible with short-acting medications. For many of those serviced by Pain Care Amici, Oxycontin has been a miracle medication.

*See Reply Br. of Amicus Curiae American Pain Foundation, The National Foundation for the Treatment of Pain, and the Ohio Pain Initiative supporting Appellants, 2004 WL 1637768, at *4.*

3. Defendants also engaged in other unlawful, unfair, and fraudulent misconduct

114. Cephalon deceptively marketed its Opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in Opioid-tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR Opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should

only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

115. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KILs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

- Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009. The CME instructed doctors that “clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility” and recommended Actiq and Fentors for patients with chronic pain. The CME is still available online.
- Cephalon’s sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.
- In December 2011, Cephalon widely disseminated a journal supplement entitled “*Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)*” to *Anesthesiology News*, *Clinical Oncology News*, and *Pain Medicine News* – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for “multiple causes of pain” – and not just cancer pain.

116. Cephalon’s deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

117. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue’s sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue

is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the *Los Angeles Times*, Purdue’s senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue had failed to take action – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue’s district manager described internally as “an organized drug ring.” In doing so, Purdue protected its own profits at the expense of public health and safety.

118. The State of New York’s settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. *See, e.g.*, Exhibit 7 ¶¶ 9-15. Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers.

119. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

C. Defendants Targeted Susceptible Prescribers And Vulnerable Patient Populations

120. As a part of their deceptive marketing scheme, Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the United States, including Arkansas. For example, Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of Opioids and therefore more likely to accept Defendants' misrepresentations.

121. Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. Defendants targeted these vulnerable patients even though the risks of long-term Opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence shows that elderly patients taking Opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. *See* Exhibit 1. The Guideline therefore concludes that there are "special risks of long-term opioid use for elderly patients" and recommends that doctors use "additional caution and increased monitoring" to minimize the risks of Opioid use in elderly patients. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with Opioids.

D. Although Defendants Knew That Their Marketing Of Opioids Was False And Deceptive, They Fraudulently Concealed Their Misconduct

122. Defendants, both individually and collectively, made, promoted and profited from their misrepresentations about the risks and benefits of Opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical evidence over the last 20 years, established that Opioids were highly addictive

and responsible for a long list of very serious outcomes. The FDA and other regulators warned Defendants of this, and Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term Opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of Defendants’ misrepresentations, and Endo and Purdue have recently entered agreements prohibiting them from making in New York some of the same misrepresentations described in this Complaint. *See* Exhibits 7, 11.

123. Moreover, at all times relevant to this Complaint, Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, Defendants disguised their own role in the deceptive marketing of chronic Opioid therapy by funding and working through third parties like Front Groups and KOLs. Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of Defendants’ false and deceptive statements about the risks and benefits of long-term Opioid use for chronic pain.

124. Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties such as KOLs and Front Groups. Defendants exerted considerable influence on these promotional and “educational” materials in e-mails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, painknowledge.org, which is run by the NIPC, did not disclose Endo’s involvement. Other Defendants, including Purdue and Janssen, ran similar website that masked their own direct role.

125. Finally, Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions,

126. Thus, Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the claims that Plaintiff now asserts on behalf of the Class. Neither Plaintiff nor any other Class Member knew of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

E. By Increasing Opioid Prescriptions And Use, Defendants' Deceptive Marketing Scheme Has Fueled the Opioid Epidemic And Devastated Arkansas Communities

127. Defendants' misrepresentation deceived doctors and patients about the risks and benefits of long-term Opioid use. Studies also reveal that many doctors and patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to Opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 Opioid patients found that four out of ten were not told Opioids were potentially addictive. Hazelden Betty Ford Foundation, *Missed Questions, missed Opportunities* (Jan. 27, 2016), available at <http://www.hazeldenbettyford.org/about-us/news-and-media/pressrelease/doctors-missing-questions-that-could-prevent-opioid-addiction>.

128. Defendants' deceptive marketing scheme caused and continues to cause doctors in Arkansas to prescribe Opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent Defendants' deceptive marketing scheme, these doctors would not have

prescribed as many Opioids. Defendants' deceptive marketing scheme also caused and continues to cause patients to purchase and use Opioids for their chronic pain believing they are safe and effective. Absent Defendants' deceptive marketing scheme, fewer patients would be using Opioids long-term to treat chronic pain, and those patients using Opioids would be using less of them.

129. Defendants' deceptive marketing has caused and continued to cause the prescribing and use of Opioids to explode. Indeed, this dramatic increase in Opioid prescriptions and use corresponds with the dramatic increase in Defendants' spending on their deceptive marketing scheme. Defendants' spending on Opioid marketing totaled approximately \$91 million in 2000. By 2011, that spending had tripled to \$288 million.

130. The escalating number of Opioid prescriptions written by doctors who were deceived by Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic increase in Opioid addiction, overdose, and death throughout the United States and Arkansas. In August 2016, the United States Surgeon General at the time, Vivek Murthy, published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."

131. Scientific evidence demonstrates a strong correlation between Opioid prescriptions and Opioid abuse. In a 2016 report, the CDC explained that "Opioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." *Patients receiving prescription Opioids for chronic pain account for the majority of overdoses.* For these reasons,

the CDC concluded that efforts to rein in the prescribing of Opioids for chronic pain are critical “to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”

132. Contrary to Defendants’ misrepresentations, most Opioid addiction begins with legitimately *prescribed* Opioids, and therefore could have been prevented had Defendants’ representations to prescribers been truthful. In 2011, 71% of people who abused prescription Opioids got them through friends or relatives, not from pill mills, drug dealers, or the internet. Numerous doctors and substance abuse counselors note that many of their patients who misuse or abuse Opioids started with legitimate prescriptions, confirming the important role that doctors’ prescribing habits have played in the Opioid epidemic.

133. As the FDA observed in 2016, the Opioid epidemic is getting worse, not better. Opioids are by far the most commonly prescribed class of substances in Arkansas. In 2012, Arkansas ranked ***eighth in the nation*** for prescriptions of Opioid medications. *See AR Gets \$8M to Fight Opioid Addiction*, ArkansasMatters.com (May 2, 2017, 11:14 AM) (submitted as Exhibit 14 to this Complaint), <http://arkansasmatters.com/news/local-news/ar-gets-8m-to-fight-opioid-addiction/704771972>. During this same time period, the number of deaths in the state from drug overdose increased by 13.5 percent. *See* Exhibit 5. According to one physician at UAMS, there are “way too many people in the state . . . receiving opioid treatment for chronic pain. Opioids have not been show[n] to be effective for the treatment of chronic pain.” *Doctor Warns of Epidemic of Opioid Addiction in Arkansas*, ArkansasNews.com (June 14, 2016, 4:29 AM) (submitted as Exhibit 15 to this Complaint), <http://arkansasnews.com/news/arkansas/doctor-warns-epidemic-opioid-addiction-arkansas>.

134. Opioid-related emergencies are rising at such a rapid pace that cities and counties in Arkansas are unable to keep up logistically and financially. Emergency rooms within the state

are “facing an epidemic of prescription medication abuse, and that means an epidemic of overdoses. Men, women, children of all ages – paramedics say they’ve seen it all.” Exhibit 5. Captain Shawn Firestine of the Crawford County Sheriff’s Office adds that the ramifications of heroin abuse – a spinoff of the Opioid crisis, *see* Exhibit 6 – act to “strain” public resources, inasmuch as “money spent on new roads, building new parks or jails, city complexes, and so on, will be diverted by the states to go toward medical care and so forth for addicts.” *Id.*

135. Defendants’ deceptive marketing scheme has also had a significant detrimental impact on children in Arkansas. The overprescribing of Opioids for chronic pain has made the drugs more accessible to school-aged children, who come into contact with Opioids after they have been prescribed to friends or relatives in the same household. In 2013, *Arkansas had the highest rate in the country* of prescription drug abuse among teens. *Fighting the Opioid Epidemic in Arkansas*, KFSM5 News (May 20, 2017, 9:55 PM) (submitted as Exhibit 16 to this Complaint), <http://5newsonline.com/2017/05/19/fighting-the-opioid-epidemic-in-arkansas>. What is more, emergency responders in Arkansas have treated younger children for overdoses after they have mistakenly ingested Opioids prescribed for adults. *See* Exhibit 5.

136. The overprescribing of Opioids for chronic pain caused by Defendants’ deceptive marketing scheme has also resulted in a dramatic rise in the number of infants in Arkansas who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome (“NAS”). These infants face painful withdrawal and may suffer long-term neurologic and cognitive impacts. Babies with NAS typically require extensive hospital stays as they withdraw.

137. The number of emergency medical services (“EMS”) runs for suspected Opioid-related overdose has also increased. As that has occurred, the utilization of Naloxone (“Narcan”),

a drug used to reverse Opiate induced overdoses, has risen dramatically. For example, paramedics in Crawford County, with a population around 61,000, administer Narcan no fewer than ten times a month. *See* Exhibit 5.

138. Defendants' creation, through false and deceptive misrepresentations and other unlawful and unfair conduct, of a virtually limitless Opioid market has significantly harmed Class Members throughout Arkansas. Defendants' success in extending the market for Opioids to new patients and chronic pain conditions has created an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury. It has been estimated that 60% of the Opioids that are abused come, directly or indirectly, through doctors' prescriptions. Nathaniel P. Katz, *Prescription Opioid Abuse: Challenges and Opportunities for Payers*, Am. J. Managed Care 5 (Apr. 19, 2013) ("The most common source of abused [Opioids] is, directly or indirectly, by prescription."), *available at* <http://www.ajmc.com/publications/issue/2013/2013-1-vol19-n4/Prescription-Opioid-Abuse-Challenges-and-Opportunities-for-Payers> (submitted as Exhibit 17 to this Complaint).

139. Law enforcement agencies have increasingly associated prescription drug abuse with violent and property crimes. Despite strict federal regulation of prescription drugs, local law enforcement agencies are faced with increasing diversion from legitimate sources for illicit purposes, including: doctor shopping, forged prescriptions, falsified pharmacy records, and employees who steal from their places of employment. The Opioid epidemic has prompted a growing trend of crimes against pharmacies including robbery and burglary. In fact, a 2005 study by The Center on Addiction and Substance Abuse at Columbia University revealed that, by that time, 20.9% of pharmacies nationwide had stopped stocking certain medications such as OxyContin and Percocet, in order to protect themselves from robbery. The ongoing diversion of

prescription narcotics creates a lucrative marketplace. *See* Exhibit 5 (confirming that Opioids are “hot on the black market”).

140. The rise in Opioid addiction caused by Defendants’ deceptive marketing scheme has also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year previously abused prescription drugs. Individuals who are addicted to prescription Opioids often transition to heroin because it is a less expensive, readily available alternative that provides a similar high. *See, e.g.*, Exhibit 6 (“One of the reasons heroin is making a come back is because people are so addicted to pharmaceuticals – opiates and opioids, and heroin is cheaper.” (quotation omitted)).

141. The costs and consequences of Opioid addiction are staggering. Prescription Opioid misuse, abuse, and overdose have an enormous impact on the health and safety of individuals as well as communities at large, as the consequences of this epidemic reach far beyond the individual who is addicted. Some of the repercussions for individuals include job loss, loss of custody of children, physical and mental health problems, homelessness, and incarceration. This results in instability in communities already in economic crisis and contributes to increased demand on community services such as hospitals, courts, child services, treatment centers, and law enforcement.

142. Defendants knew and should have known about these harms that their deceptive conduct has caused. Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding. Defendants also had access to and watched carefully government and other data that tracked the explosive rise in Opioid use,

addiction, injury, and death. They knew – and, indeed, intended – that their misrepresentations would persuade doctors to prescribe and patients to use their Opioids for chronic pain.

143. Defendants' actions are not permitted nor excused by the fact that their drug labels (with the exception of the Actiq/Fentora labels) may have allowed or did not exclude the use of Opioids for chronic pain. FDA approval of Opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of Opioids. Indeed, Defendants' misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

144. Nor is Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also were able to harness and hijack what doctors wanted to believe: Namely, that Opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

145. While the use of Opioids has taken an enormous toll on Class Members, Defendants have realized blockbuster profits. In 2014 alone, Opioids generated \$11 billion in revenue for drug companies like Defendants. Indeed, financial information indicates that each Defendant experienced a material increase in sales, revenue, and profits from the false and deceptive misrepresentations and other unlawful and unfair conduct described above.

V. CLASS ACTION ALLEGATIONS

146. Plaintiff brings this action as a class action, on behalf of the following classes, pursuant to Rule 23 of the Federal Rules of Civil Procedure:

Rule 23(b)(3) Class

All persons who were prescribed in Arkansas, from the time period beginning June 30, 2012 and ending June 30, 2017, opioids manufactured by Defendants (including, but not limited to, Oxycontin, Percocet, Oxycodone, and Hydrocodone) and who subsequently (1) received medical attention for a drug overdose involving opioids or opiates, and/or (2) sought treatment for addiction related to Opiate prescriptions;

Rule 23(b)(2) Class

All persons who were prescribed in Arkansas, from the time period beginning June 30, 2012 and ending June 30, 2017, opioids manufactured by Defendants (including, but not limited to, Oxycontin, Percocet, Oxycodone, and Hydrocodone).

Throughout this Complaint, the Rule 23(b)(2) and (b)(3) classes are collectively referred to as the “Class.” The two classes are independently referred to as the “Rule 23(b)(2)” or the “Rule 23(b)(3)” Class.

147. The following persons are expressly excluded from the Class: (1) Defendants and their subsidiaries, affiliates, and controlled persons; (2) officers, directors, agents, servants, or employees of Defendants, and the immediate family members of any such person; (2) all persons who make a timely election to be excluded from the proposed Class; (3) governmental entities; and (4) the Court to which this case is assigned and its staff.

148. This action can be maintained as a class action because there is a well-defined community of interests in the litigation and the proposed Class is easily ascertainable.

149. Numerosity: In 2016 alone, Arkansans filled over 1.7 million prescriptions for Opioids (*see* Exhibit 4), and the CDC has confirmed that patients receiving prescription Opioids for chronic pain account for the majority of Opioid overdoses. Based on this sort of publicly available data, it is estimated that the Class numbers in the thousands, and that joinder of all Class Members is impracticable.

150. Common Questions Predominate: This action involved common questions of law and fact applicable to each Class Member that predominate over questions that affect only individual Class Members. Thus, proof of a common set of facts will establish the right of each Class Member to recover. Questions of law and fact common to each Class Member include:

- a. Whether Defendants engaged in unlawful, unfair, or deceptive business practices by misrepresenting the addictive nature of Opiates they manufactured, marketed, and distributed;
- b. Whether Defendants violated the ADTPA through their course of unfair and/or deceptive conduct as alleged in this Complaint;
- c. Whether Defendants' unlawful, unfair, and deceptive practices harmed Plaintiff and the Class;
- d. Whether Defendants' conduct in violation of the ADTPA was willful and wanton;
- e. Whether Plaintiff and the Class have been damaged by the unlawful actions of the Defendants and the amount of damages to the Class;
- f. Whether Defendants were unjustly enriched by their deceptive practices; and
- g. Whether Defendants acted or refused to act on grounds that apply generally to the Class, so that medical monitoring relief is appropriate respecting the Class as a whole.

151. Typicality: Plaintiff's claims are typical of the claims of the Plaintiff received during the Class Period a prescription for Opioids and subsequently sought and received treatment for an addiction involving Opioids. Defendants' unlawful, unfair, and/or fraudulent actions concern the same business practices described in this Complaint, irrespective of whether they occurred or were experienced. Plaintiff and each Class Member sustained similar injuries arising out of Defendants' conduct in violation of Arkansas law. The injuries of each member of the Class were caused directly by Defendants' wrongful conduct. In addition, the factual underpinning of Defendants' misconduct is common to all Class Members and represents a common thread of misconduct resulting in injury to all members of the Class. Plaintiff's claims arise from the same

practices and course of conduct that give rise to the claims of each member of the Class and are based on the same legal theories.

152. Adequacy: Plaintiff will fairly and adequately protect the interests of the Class. Neither Plaintiff nor Plaintiff's counsel have any interests that conflict with or are antagonistic to the interests of the Class. Plaintiff has retained competent and experienced class action attorneys to represent his interests and those of the members of the Class. Plaintiff and Plaintiff's counsel have the necessary financial resources to adequately and vigorously litigate this class action, and Plaintiff and counsel are aware of their fiduciary responsibilities to members of the Class and will diligently discharge those duties by seeking the maximum possible recovery for the Class.

153. Superiority: There is no plain, speedy, or adequate remedy other than by maintenance of this class action. The prosecution of individual remedies by members of the Class will tend to establish inconsistent standards of conduct for Defendants and result in the impairment of each Class Member's rights and the disposition of Class Members' interests through actions to which they were not parties. Class action treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of effort and expense that numerous individual actions would engender. Further, as the damages suffered by individual members of the class may be relatively small, the expense and burden of individual litigation would make it difficult or impossible for individual members of the Class to redress the wrongs done to them, while an important public interest will be served by addressing the matter as a class action. Class treatment of common questions of law and fact would also be superior to multiple individual actions or piecemeal litigation in that class treatment will conserve the resources of the Court and the litigants, and will promote consistency and efficiency of adjudication.

154. Predominance: The prerequisites to maintaining a class action pursuant to Rule 23 of the Arkansas Rules of Civil Procedure are met, in that questions of law or fact common to each Class Member predominate over any questions affecting only individual members, and a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.

155. Medical Monitoring/Declaratory and Injunctive Relief. All of the requirements for Rule 23(b)(2) class certification are satisfied. First, as set forth above, Plaintiff has satisfied the requirements of Rule 23(a) including numerosity, commonality, typicality, and adequacy of representation. Rule 23(b)(2) requirements are satisfied in that the Defendants have acted or refused to act on grounds generally applicable to all Class Members, thereby making appropriate final declaratory and injunctive relief with respect to the Rule 23(b)(2) Class as a whole. The 23(b)(2) Class Members are entitled to injunctive relief ordering diagnostic monitoring, clinical examinations, and education programs. Such relief will provide a remedy for Defendants' uniform acts and omissions toward the 23(b)(2) Class.

156. Plaintiff and Plaintiff's counsel are unaware of any difficulties that are likely to be encountered in the management of this action that would preclude its maintenance as a class action.

VI. CAUSES OF ACTION

FIRST CAUSE OF ACTION

(Violation of Ark. Code Ann. §§ 4-88-101 to -115)

157. Plaintiff repeats and realleges each of the above allegations as if fully set forth again.

158. Defendants' conduct constitutes unlawful deceptive and unconscionable trade practices. Defendants' conduct was consumer oriented and this conduct had broad impact on consumers at large. Defendants made materially misleading misrepresentations regarding the addictive nature of Opioids they manufactured, marketed, and distributed.

159. Defendants made materially misleading misrepresentations about Opioids they sold, and which were prescribed, in Arkansas during the Class Period.

160. As fully described above, by advertising, marketing, distributing, and selling Opioids which they had misrepresented to Plaintiff and other members of the Class who received prescriptions for Defendants' misrepresented Opioids, Defendants engaged in unlawful deceptive and unconscionable trade practices.

161. Defendant's misleading misrepresentations regarding Opioids they manufactured, marketed, and distributed were material, and they were likely to deceive reasonable consumers and health care providers.

162. Plaintiff, other members of the Class, and health care providers were deceived by Defendants' material misrepresentations as described in this Complaint.

163. Defendants have engaged in unlawful deceptive and unconscionable trade practices.

164. Plaintiff and other members of the Class who were prescribed and purchased Defendants' Opioids in Arkansas were injured by Defendants' unlawful deceptive and unconscionable trade practices.

165. The injuries suffered by Class Members were proximately caused by Defendants' deceptive conduct. But for the deceptive scheme perpetrated by Defendants, which included material misrepresentations made by Defendants, their Front Groups, and the KOLs, Class Members would not have paid for Opioid prescriptions for chronic pain. In addition, but for Defendants' deceptive conduct, Class Members would not have paid for treatment addressing addiction involving Opioids. Class Members' injuries and damages were directly caused by Defendants' deceptive conduct.

166. As a result of Defendants' unlawful deceptive and unconscionable trade practices, Plaintiff and the members of the Class, pursuant to Ark. Code Ann. §§ 4-88-107 to -108, -113, are entitled to damages and such other orders and judgments which may be necessary to disgorge Defendants' ill-gotten gains and to restore to Plaintiff and Class Members any money paid for Defendants' materially misrepresented Opioids. Plaintiff and Class Members are also entitled to collect from Defendants damages they suffered by paying for treatment to address addiction involving Opioids and/or opiates.

SECOND CAUSE OF ACTION
(Unjust Enrichment)

167. Plaintiff repeats and realleges each of the above allegations as if fully set forth again.

168. As a result of Defendants' unlawful and deceptive actions described above, Defendants were enriched at the expense of Plaintiff and the Class through payment for Opioids which Defendants had materially misrepresented.

169. In the circumstances, it would be against equity and good conscience to permit Defendants to retain the ill-gotten benefits that they received from Plaintiff and the Class, in light of the fact that the Opioids prescribed for and purchased by Plaintiff and Class Members were far more addictive than Defendants misrepresented them to be. As such, it would be unjust and inequitable for Defendants to retain the benefit without restitution to the Plaintiff and the Class for monies paid to Defendants for misrepresented Opioids.

THIRD CAUSE OF ACTION
(Medical Monitoring and other Injunctive Relief)

170. Plaintiff repeats and realleges each of the above allegations as if fully set forth again.

171. Through the massive overprescription of Opioids that has occurred as a result of Defendants' deceptive conduct, the Rule 23(b)(2) Class Members are at increased risk for addiction and/or overdose.

172. Early detection of problematic drug use – through examination and testing – has significant value for Rule 23(b)(2) Class Members because such detection will help them monitor and minimize the harm therefrom.

173. Due to the receipt of Opioid prescriptions by the Rule 23(b)(2) Class Members, surveillance in the form of periodic medical examinations is reasonable and necessary, because such surveillance will provide early detection and diagnosis of the often cunning and baffling warning signs for drug addiction, which – once it takes hold – is so powerful that it destroys and ends lives. As a remedy for the deceptive and unconscionable conduct alleged in this Complaint, Defendants should be required to fund a medical monitoring program designed to identify and combat early signs of problematic drug use and addiction.

VII. JURY DEMAND

Plaintiff hereby demands a trial by jury of his claims.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually, and on behalf of all other similarly situated persons, prays for judgment against Defendants as follows:

A. For an order certifying this case as a class action and appointing Plaintiff and Plaintiff's counsel to represent the Class;

B. For an order awarding, as appropriate, damages, restitution, or disgorgement to Plaintiff and the Class including all monetary relief to which Plaintiff and the Class are entitled;

C. For declaratory, injunctive, and/or other equitable relief which orders Defendants to establish programs to educate Arkansans on the risks associated with Opiate prescriptions;

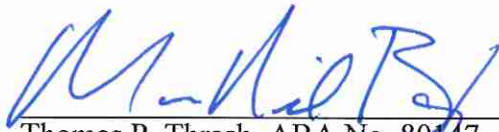
D. For a preliminary injunction, permanent injunction, or declaratory judgment to implement testing of Rule 23(b)(2) Class Members to detect early signs of problematic drug use and addiction;

E. For an order awarding pre-judgment and post-judgment interest; and

F. For an order awarding attorneys' fees and costs.

DATED: June 29, 2017

Respectfully submitted,

A handwritten signature in blue ink, appearing to read 'M. Thrash', is written over a horizontal line.

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